



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Reg. Number: 81242-1

Date of Issuance: MAR 10 2011

Term of Issuance: Conditional

Name of Pesticide Product: Ygiene 206

NOTICE OF PESTICIDE:

[x] Registration
Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

BioNeutral Group, Inc.
211 Warren Street
Newark, NJ 07103

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(a) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.
2. Make the labeling changes listed below before you release the product for shipment:
a. Revise the "EPA Registration Number to read, "EPA Reg. No. 81242-1".

Signature of Approving Official

Handwritten signature of Marshall Swindell

Marshall Swindell
Product Manager Team-33
Regulatory Management Branch I
Antimicrobials Division (7510P)

Date:

MAR 10 2011

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- b. To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characterizes study must be provided. The Agency acknowledges that testing is currently underway.
- c. On page four under Direction For Use, the term "residential" must be removed.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. Submit one (1) copy of your final printed labeling prior to release of this product for shipment. If you have any questions concerning this letter, please contact Abigail Downs at (703) 305-5259.

Sincerely,



Marshall Swindell  
Product Manager Team-33  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Enclosure: (Stamped Label) (Efficacy Addendum dated 01/24/2011) (Acute Toxicity Review dated 02/18/2011) (Product Chemistry Review dated 12/01/2010)

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{MASTER LABEL}

{All text in brackets [xxx] is optional & may or may not be included on a printed label.}

# Ygiene™ 206

Ygiene™ 206 is for use as a disinfectant, fungicide, and sporicide/sterilant on non-porous hard surfaces in commercial, hospital, and medical environments.

### ACTIVE INGREDIENTS:

Hydrogen peroxide .....	6.14%
Peracetic acid.....	0.60%
Other Ingredients.....	93.26%
Total.....	100%

## DANGER

KEEP OUT OF REACH OF CHILDREN

FIRST AID	
<b>IF IN EYES</b>	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, and then continue rinsing. Call a poison control center or physician for treatment advice
<b>IF SWALLOWED</b>	Call a poison control center or physician immediately after treatment for advice. Have a person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or physician. Do not give anything by mouth to an unconscious person.
<b>IF ON SKIN OR CLOTHING</b>	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or physician for treatment advice.
<b>IF INHALED</b>	Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or physician for further treatment advice.
<b>Have the product container with you when calling a poison control center or going for treatment.</b>	
<b>FOR EMERGENCY MEDICAL INFORMATION CALL TOLL FREE: 1-800-222-1222</b>	
<b>NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.</b>	

Manufactured by:  
 BioNeutral Group Inc.  
 211 Warren Street  
 Newark, New Jersey 07103

ACCEPTED  
 with COMMENTS  
 in EPA Letter # 1003

MAR 10 2011

Under the Federal Insecticide,  
 Fungicide, and Rodenticide Act as  
 amended, for the pesticide,  
 registered under EPA Reg. No.

81242-1

Net Contents:  
 EPA Reg. No.: 81242-R  
 EPA Est. No.: 87275-NJ-001

{MASTER LABEL}

{All text in brackets [xxx] is optional & may or may not be included on a printed label.}

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

**DANGER. CORROSIVE.** Causes irreversible eye damage. Do not get in eyes, and avoid contact with skin or on clothing. Harmful if swallowed. Wear protective eyewear (goggles, face shield, or safety glasses), clothing, and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuses.

#### PHYSICAL AND CHEMICAL HAZARDS

Strong Oxidizing Agent. Corrosive. Never mix or use this product in combination with other sanitizers, cleaners or organic substances.

#### ENVIRONMENTAL HAZARDS

This pesticide is toxic to birds, fish and aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National pollutant Discharge Elimination System (NPDES) permit and permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact you State Water Board or Regional Office at the EPA.

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### STORAGE AND DISPOSAL

#### Pesticide Storage

Do not return Ygiene™ 206 to the original container after it has been removed. Avoid all contaminants, especially dirt, reducing agents and metals. Contamination may reduce shelf life and can induce decomposition. In case of decomposition douse container with cool water and dilute with large volumes of water. Avoid damage to containers. Keep container closed at all times when not in use. Keep container out of direct sunlight.

#### Procedure for Leaks or Spills

Stop leak if this can be done without risk. Shut off ignition sources: no flames, smoking, flares, or spark producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water.

#### Pesticide Disposal

Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide mixture, or rinsate is in violation of Federal Law. If these wastes cannot be disposed of by use according to label instruction, contact your State Pesticide or Environmental Control Agency, or Hazardous Waste representative at the nearest EPA Regional Office for guidance. If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements.

#### Container Disposal: Nonrefillable container. Do not reuse or refill this container.

[1 gallon or less: If empty, securely wrap original container in several layers of newspaper and discard in trash or offer for recycling if available. If partly filled, call your local solid waste agency for disposal instructions.]

[OR]

[Drums and Totes: Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times.

Then offer for recycling if available or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. Empty drums and bottles are not returnable to BioNeutral unless special arrangements have been made.]

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{MASTER LABEL}

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### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**Suitable for use on most hard, non-porous surfaces in residential, commercial or health care sites including:**

Hospitals	Academic Facilities	Airports
Health Care Facilities	University Laboratories	Hotels
Autopsy Facilities	Recreational/Entertainment Facilities	Industrial Facilities
Animal Hospitals and Veterinary Facilities	Sports/Physical Fitness Facilities	Retail and Wholesale Establishments
Farms	Bars/Restaurants/Cafeterias	Spas
Animal Life Science Laboratories	Office Buildings	Salons
Animal Shelters/Care Facilities	Funeral Homes	Dental Facilities

**Suitable for Use as a Disinfectant and Fungicide** on most hard, non-porous surfaces (e.g., linoleum, vinyl, sealed asphalt, sealed nonporous concrete, sealed nonporous brick and stone, glazed porcelain and ceramic tile, plastic (vinyl, polyethylene, and polypropylene), and glass). This product is compatible with stainless steel and aluminum surfaces. If this product is intended to be used on other metal surfaces it is recommended that you apply this product to a small test area to determine compatibility before proceeding with its use. Areas of appropriate use as a disinfectant and/or fungicide include:

Appliances	Crutches	Tables
Attics	Desks	Tires
Banisters/Hand railings	Devices and equipment – non-electrical and non-critical health care related	Toys
Bathrooms/Restrooms – fixtures/appliances	Doors – handles/knobs	Walls
Benches – bench tops	Fans	Wheels
Bottles	Faucets/Spickets	Windows – frames/sills
Cabinets/Shelves	Fences/Gates/Partitions	Window glass
Cages	Floors	Seats
Cans	Garbage/Trash/Refuse/Waste – cans/bins/chutes/carriers/compactors	Remote Controllers
Carts	Kitchens – appliances/fixtures	Phones
Chairs/Wheelchairs	Light – switches/covers	Railings
Containers	Lockers	Ceilings
Coolers	Poles/Posts	
Countertops	Stairs/Steps	

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**Suitable for Use as a Disinfectant and Fungicide** on most hard, non-porous surfaces in transportation applications, including:

Cars
Ambulances/Patient transfer vehicles
Trucks/Fire trucks
Taxis/Buses/Subways
Other public transportation and mass transit
Trains/Planes/Ships/Boats/Cruise Ships
Bicycles

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**To Disinfect:**

Ygiene™ 206 is an effective broad spectrum hospital or medical environment disinfectant against gram positive and gram negative bacteria (i.e., *Staphylococcus aureus*, Methicillin Resistant *Staphylococcus aureus* (MRSA), *Salmonella enterica*, and *Pseudomonas aeruginosa*). Heavily soiled surfaces must be pre-cleaned prior to disinfection; remove gross soil and then wash with Ygiene™ 206 followed by thorough potable water rinse. Apply this product by wiping, mopping or as a coarse spray. Allow surface to remain thoroughly wet for at least 2 minutes, then wipe with a clean cloth or allow to air dry. Ygiene™ 206 may be used in general (household) commercial and medical environments to clean, disinfect, and deodorize inanimate surfaces.

**To Kill Fungi:**

Ygiene™ 206 is an effective Fungicide against *Trichophyton mentagrophytes* and *Aspergillus niger*. Heavily soiled surfaces must be pre-cleaned prior to disinfection; remove gross soil and then wash with Ygiene™ 206 followed by thorough potable water rinse. Apply this product by wiping, mopping or as a coarse spray. Allow surface to remain thoroughly wet for at least 2 minutes, then wipe with a clean cloth or allow to air dry. Reapply weekly or when mold and mildew growth reappears.

**Use as a Sporicide (Sterilant)** {this use will only appear on container sizes ≥ 1 quart}

Ygiene™ 206 is not to be used as a sterilant on any surface or instrument that is introduced directly into the human body, either into or in contact with the bloodstream or other normally sterile areas of the body. This product is not approved for use as a sterilant on electrical and critical/semi-critical health care related devices.

Ygiene™ 206 is an effective sporicide against *Bacillus subtilis* and *Clostridium sporogenes* when used as directed.

This product is suitable for use as a sporicide (sterilant) on most hard non-porous materials and articles. It is compatible with stainless steel, aluminum, linoleum, glazed porcelain and ceramic tile, plastic (vinyl, polyethylene, and polypropylene), and glass. [If this product is intended to be used on other metal surfaces it is recommended that you apply this product to a small test area to determine compatibility before proceeding with its use.]

**Sterilization by Flooding:** Flooding application may be used in situations where a large volume can be spread over a floor or pan surface where the liquid can be contained for the entire contact time without complete evaporation. Remove gross soil from the surface to be sterilized. Use enough product to cover the surface to be treated, ensuring that the surface is covered with the product for the entire 20 minute contact time. Reapply product if it begins to dry out during the 20 minute contact time.

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**Sterilization by Immersion:** Immersion may be used to treat immersible non-electrical articles, tools, and devices that are not related to critical/semi-critical health care (e.g., jewelry, keys, eyewear, small containers, coins, toys, etc.). Remove any obvious debris or organic material from the surface or object to be sterilized. Dismantle devices prior to pre-cleaning, if necessary. Pour appropriate amount of Ygiene™ 206 into a tray or receptacle that will hold the items to be treated and allow for their complete immersion in, and surface contact with, the solution. Immerse articles for a minimum of 20 minutes. Transfer the treated articles to a water rinse bath to remove the treatment solution. Dry the Ygiene™ 206 treated articles prior to reassembly or use.

**Note:** Ygiene™ 206 may cause bleaching of treated surfaces; test item if unsure. Before using Ygiene™ 206 on metal surfaces other than stainless steel and aluminum, it is recommended that the product be tested on a small area to determine compatibility.

This product must not result in direct or indirect contamination of food products.

**WARRANTY**

**BioNeutral Group Inc.** warrants that this product complies with the specifications expressed on the label. To the extent consistent with applicable law, **BioNeutral Group Inc.** makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose.

{The following statement and its corresponding table is optional language}

{This product has been demonstrated efficacy against the following specific organisms:}

Organism	ATCC No.	Contact Time
<i>Pseudomonas aeruginosa</i>	15442	2 minutes
<i>Salmonella enterica</i>	10708	90 seconds
<i>Staphylococcus aureus</i>	6538	90 seconds
Methicillin Resistant <i>S. aureus</i> (MRSA)	33592	90 seconds
<i>Bacillus subtilis</i>	19659	20 minutes
<i>Clostridium sporogenes</i>	3584	20 minutes
<i>Trichophyton metagrophytes</i>	9533	2 minutes
<i>Aspergillus niger</i>	16404	2 minutes

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